



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Hitachi Cable America Inc.,

High Performance Medical Solutions

Division 15 Gray Lane Ashaway Rhode Island 02804

USA

Holds Certificate No: FM 633068

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Manufacture of extruded tubing, components and assemblies specializing in medical applications and contract manufacturing of medical devices.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2015-04-14 Latest Revision Date: 2022-05-10 Effective Date: 2022-02-02 Expiry Date: 2025-02-01

Page: 1 of 2

bsi.



...making excellence a habit."

Certificate No: FM 633068

Location Registered Activities

Hitachi Cable America Inc., High Performance Medical Solutions Division 15 Gray Lane Ashaway Rhode Island

02804 USA Manufacture of extruded tubing, components and assemblies specializing in medical applications and contract manufacturing of medical devices.

Hitachi Cable America Inc., High Performance Medical Solutions Division 75 Frontage Rd. North Stonington Connecticut 06359 USA Manufacture, inspection, and packaging of braided tube.



Original Registration Date: 2015-04-14 Latest Revision Date: 2022-05-10 Effective Date: 2022-02-02 Expiry Date: 2025-02-01

Page: 2 of 2

This certificate remains the property of BSI and shall be returned immediately upon request. An electronic certificate can be authenticated <u>online</u>. Printed copies can be validated at www.bsigroup.com/ClientDirectory To be read in conjunction with the scope above or the attached appendix.